Constitution of PAROS EXCO

What is PAROS?

PAROS stands for Pan-Asian Resuscitation Outcomes.

Governance of PAROS

PAROS EXCO: The PAROS Executive Committee (EXCO) is formed to manage the PAROS clinical research network (CRN). PAROS EXCO will provide overall direction and be the decision-maker on all major issues pertaining to the acceptance, management, budgeting, conduct, authorship and publication of trials or other CRN studies.

What constitutes the PAROS EXCO?

The PAROS EXCO will comprise of the following:

- Chair
- 3 Co-Chairs
- Trial Co-ordinating Centre Representative (Singapore Clinical Research Institute COO or designee)
- Up to 2 representatives from each participating country
- Network Biostatistician (non-voting)
- Clinical Research Network Manager (non-voting)
- Training & Administrative Coordinator (non-voting)

The Executive Committee Chair and Co-Chairs will be recognized disease experts in the Asia Pacific with established publication records and expertise in the conduct of multi-site trials. The Chair and Co-Chairs may or may not also function as the Study Principal Investigator (PI) and Co-PI for particular studies. Both Chair and Co-Chairs will be elected every 3 years. Only Co-Chairs who have completed 1 term of service will be eligible to be elected as Chair.

The Executive Committee will also comprise of up to 2 country PIs per participating country; they will be nominated by the country represented. The PAROS CRN will have the autonomy to decide to rotate persons who serve as Executive Committee, Chair or Co-Chair (i.e. Network PI and Co-PI) for 3 years term. In addition, the Executive Committee will include the Network Biostatistician, SCRI COO or designee, and a PAROS Network Clinical Manager, and as needed for a PAROS network Administrative Manager (ex officio).

The PAROS Executive Committee will be served by two additional sub committees, which will be formed for each study conducted on the PAROS CRN: the Publication Committee, and the Operations Committee.

Publication Committee (PC)

Network PC will be designated for each study by the Executive Committee. The PC will have 6-8 members including the Study Biostatistician. The PC is chaired by the Study PI or Co-PI and Co-Chaired by the Study Biostatistician. This committee oversees reviews, provides written critiques, and gives final approval for all journal article submissions from the study. It also designates materials that go on the public section of the study Website and, depending on the Executive Committee, may or may not provide authorization for any poster or other public presentation of the primary study, secondary analyses, or ancillary studies.

The PC may contract with a medical writer when needed, though the first author of any manuscript must write the first draft. Once a manuscript is submitted, correspondences are between the corresponding author and the journal. Final versions of the manuscript, if revisions are required, must go through and receive approval from the Publication Committee.

The PC proposes the rules of authorship to the Executive Committee OR the Executive Committee and Study PI establish the rules of authorship, in either case before study initiation. The general guidance is that for multisite studies, the Study PI and Co-PI, the Study Biostatistician, Assistant Biostatistician and/or Data Manager, Project Manager, and all site PIs are co-authors. Site Co-PIs will be included whenever the position is earned and is feasible given publication limitations.

Secondary analyses are typically assigned to Clinical Site PIs or Co-PIs. In these cases, the Study PI and Co-PI become senior authors. These publications continue to include the Biostatistician and other Data Center (i.e. SCRI) personnel involved in study management if they have made substantive scientific contributions to the manuscripts. Specific numbers and types of slots for co-authors will be stipulated prior to study initiation for the primary and planned secondary analyses. The PC (or the Executive Committee – depending on the Network and Study) will review, approve and recommend author slots for additional (unplanned) secondary analyses.

Operation Committee (OC)

The Operations Committee will be Co-Chaired by the Study Co-PI and the Head of the Trial Co-ordinating Centre (SCRI COO or his designee). The Committee will include the Clinical Research Network Clinical Manager, a Study Project Manager, possibly a regulatory person and possibly an Administrative Manager. The role of the OC would be to oversee and make decisions (or provide recommendations to the Executive Committee) pertaining to all

operational aspects of running the study, e.g. issues pertaining to data management, study monitoring and regulatory considerations.

Network Membership

The membership to a PAROS CRN will be defined by its Executive Committee on the basis of participation which will be reviewed annually. The participation refers mainly to contribution of patients but may also include contributions to study protocol, and other inputs to the study/network.

It is important that the Executive Committee members have the interest, expertise, as well as ability to contribute to PAROS CRN. Hence continued membership is dependent on contribution to various aspects of the CRN's roles. For example, a clinical site PI would be expected to contribute a minimum number (to be decided by PAROS CRN) of patients to any trials conducted by the network trial in a 3-year period. In addition, a clinical site would also be expected to response to queries within 2 weeks. Alternatively but not exclusively, Executive Committee members could also contribute to clinical trial design, funding or management. Executive Committee members would be allowed to fully participate in the decision making process of the PAROS CRN.

While any clinical members of the Committee may propose a new study, Study PI who has proposed the study would be expected to secure the required funding to conduct the study. In the absence of such funding, the PAROS CRN has no obligation to proceed with the trial.

Type of memberships:

It is envisaged that there will be two types of memberships:

a. Ordinary members: any clinician who has enrolled three or more patients into any clinical trial conducted by the PAROS CRN. They can be invited to attend the General Meeting or Scientific Meetings of the PAROS CRN.

b. Associate members: interested individuals who may be clinicians, para-clinicians, scientific staff or lay individuals. These will be kept on a mailing list to receive updates of the activities of the PAROS CRN. They may be allowed to attend General Meetings or Scientific Meetings of the PAROS CRN subject to the Executive Committee's approval.

APPENDIX A - DEFINITION OF TERMS

TERM	DEFINITION
Executive Committee (EXCO)	The Committee which is formed to manage the PAROS Clinical Research Network (CRN) to provide overall direction and be the decision-maker on all major issues pertaining to the acceptance, management, budgeting, conduct, authorship and publication of trials or other PAROS CRN studies.
Clinical Research Network (CRN)	The PAROS Clinical Research Network is a collaborative research group formed in 2010 by dedicated clinicians conducting research in Prehospital and Emergency Care (PEC) in the Asia-Pacific region.
Trial Co-ordinating Centre	Infrastructure which provides all the necessary clinical study coordination to support the PAROS CRN.
Chair	The head of the PAROS CRN who has overall responsibility for the CRN.
Co-Chair	The person who provides support to the chair on the management of the CRN.
Publication Committee (PC)	The committee which is chaired by the study PI or Co-PI and Co-chaired by the Study Biostatistician to oversee, review and provide written critiques, and to give final approval for all journal article submissions from a designated study.
Operation Committee (OC)	The committee is chaired by the study Co-PI and COO of Singapore Clinical Research Institute (SCRI) to oversee and make decisions (or provide recommendations to the Executive Committee) pertaining to all operational aspects of a designated study.
Network Biostatistician	Biostatistician who is appointed by SCRI to serve on the PAROS EXCO (may also function as the Study biostatistician for some studies).
Study Biostatistician	The Biostatistician for a particular study.
Study Principal Investigator (PI)	A person responsible for the conduct of a clinical trial, and is the responsible leader of the trial team.
Co-PI	A Co-Leader of a group of investigators to conduct a clinical trial at a trial site.
Site PI	The main study investigator to conduct a clinical trial at a trial site.
Network PI	The main investigator to lead and coordinate the conduct of clinical trials executed in the CRN.
Clinical Research Network Manager	A person who provides secretariat support for the clinical research network.
Network Administrative Manager	A person who provides administrative support for the clinical research network.
Training & Administrative Coordinator	A person who provides training support and coordination for the CRN.

Study Project Manager	A project manager is responsible for overall implementation of trial, overseeing progress of trial, trial communications; budget and cost control.
Data Management	Clinical Data Management is the technology and the processes that timely manage clinical data to produce a high quality, validated and analyzable data. Its primary objective is to ensure timely delivery of high-quality data which are necessary to satisfy both Good Clinical Practice (GCP) requirements & the statistical analysis and reporting requirements.
Study Monitoring	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), GCP, and the applicable regulatory requirement(s).